IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

STATE OF MISSISSIPPI, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, *et al.*,

Defendants.

Civil Action No. 1:22-cv-00113-HSO-RPM

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs, seven states, challenge a rule promulgated by the Centers for Medicare & Medicaid Services ("CMS") implementing part of the Merit-based Incentive Payment System ("MIPS") for physician payments under Medicare Part B. Physicians who elect to participate in MIPS may select from a long list of "clinical practice improvement activit[ies]"—of which there are currently 104 options—to qualify for payment enhancement. Plaintiffs challenge one of those activities, called "create and implement an anti-racism plan." *See* Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes, 86 Fed. Reg. 64,996, 65,969 (Nov. 19, 2021), Administrative Record (AR) 0001, 0005-6. Plaintiffs allege the rule's addition of this improvement activity is *ultra vires* because it does not relate to "clinical practice or care delivery" and has not been identified as improving such by "relevant eligible professional organizations and other relevant stakeholders," as required by the authorizing MIPS statute. 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III).

Defendants are entitled to summary judgment because the state plaintiffs lack standing and because the challenged rule was within CMS's statutory authority. First, the States lack standing because they have failed to establish harm to any legally cognizable state interest. Although this Court determined at the motion to dismiss stage that the States had a sovereign interest in the enforcement of their anti-discrimination laws, an intervening Supreme Court decision, *Haaland v. Brackeen*, 143 S. Ct. 1609, 1640 (2023), displaces this Court's earlier analysis. And, in *United States v. Texas*, 143 S. Ct. 1964, 1977 (2023), the Supreme Court also called into question this Court's earlier determination that the States were entitled to "special solicitude." But even if the States' asserted interest were cognizable for Article III standing purposes, Plaintiffs have failed to introduce evidence, as required at the summary judgment stage, of how they are harmed by the

improvement activity. The Court therefore lacks jurisdiction to consider the States' challenge and should grant Defendants' motion for summary judgment.

Second, even if this Court had jurisdiction, Plaintiffs have fallen far short of their heavy burden to establish that CMS violated a clear statutory mandate or prohibition and therefore acted *ultra vires*. There is ample evidence in the record that the creation and implementation of an anti-racism plan has been identified by "relevant eligible professional organizations and other relevant stakeholders . . . as improving clinical practice or care delivery" and has been determined by CMS to be, "when effectively executed, . . . likely to result in improved outcomes." 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III). Therefore, the creation of such an activity was within CMS's statutory authority, and Defendants are entitled to summary judgment on the merits of Plaintiffs' claim.

BACKGROUND

I. STATUTORY BACKGROUND

The statutory and regulatory background is set out in more detail in Defendants' Motion to Dismiss Plaintiffs' First Amended Complaint (ECF No. 37, at 2-8) and in the Court's March 28, 2023, Memorandum Opinion and Order (ECF No. 52, at 2-13), *see Colville v. Becerra*, No. 1:22cv113-HSO-RPM, 2023 WL 2668513, at *1-*7, but will also be summarized briefly here.

In 2015, to "improv[e] Medicare payment for physicians' services" under Medicare Part B, Congress directed the United States Department of Health and Human Services ("HHS") to create a "Merit-based Incentive Payment System" for payments for covered professional services furnished by MIPS eligible professionals on or after January 1, 2019. Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), Pub. L. No. 114-10, § 101(c)(1), 129 Stat. 87, 92 (2015), *codified at* 42 U.S.C. § 1395w-4(q). Specifically, HHS must link payments to performance in four categories that focus on the quality and cost of patient care provided by the MIPS eligible

professional—quality, resource use, clinical practice improvement activities, and meaningful use of certified electronic health records ("EHR") technology (which CMS now refers to as "promoting interoperability"). 42 U.S.C. § 1395w-4(q)(2); *see* 83 Fed. Reg. 59,452, 59,720 (Nov. 23, 2018). Starting in 2019, positive, neutral, or negative adjustments to payments to MIPS eligible professionals are determined based on their performance in these four categories, with adjustments varying to maintain budget neutrality. 42 U.S.C. § 1395w-4(q)(6).

The MIPS performance category at issue in this suit is the "clinical practice improvement activities" or "improvement activities" category. First Am. Compl. ¶ 44 (ECF No. 28). MACRA defines "clinical practice improvement activity" as "an activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes." 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III). The statute further specifies that the performance category of clinical practice improvement activities shall include subcategories "specified by the Secretary," but must include those of "expanded practice access," "population management," "care coordination," "beneficiary engagement," "patient safety and practice assessment," and "participation in an alternative payment model," and lists examples for each subcategory. *Id.* § 1395w-4(q)(2)(B)(iii). The improvement activities performance category accounts for 15 percent of a MIPS eligible professional's MIPS final score,[1] subject to HHS's authority to assign different scoring weights in certain circumstances. *Id.* § 1395w-4(q)(5)(E)(i)(III), (F).

[1] The quality and resource use performance categories each account for 30% of the final score and the promoting interoperability category accounts for 25%. 42 U.S.C. § 1395w-4(q)(5)(E)(i)(I), (II), (IV).

Regarding judicial review, 42 U.S.C. § 1395w-4 further provides that "there shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise of" "[t]he identification of measures and activities specified under paragraph (2)(B) . . . ." 42 U.S.C. § 1395w-4(q)(13)(B).

II. REGULATORY BACKGROUND

To the subcategories identified by MACRA under the "clinical practice improvement activities" performance category, HHS, through CMS, added via rulemaking some additional subcategories, including the subcategory of "Achieving Health Equity." 42 C.F.R. § 414.1355(c)(7); *see* 81 Fed. Reg. 77,008, 77,188-90 (Nov. 4, 2016). CMS also yearly publishes and regularly updates an inventory of clinical practice improvement activities that MIPS eligible professionals (referred to by CMS as "clinicians," *see* 42 C.F.R. § 414.1305) can complete under this MIPS performance category. *See, e.g.,* 81 Fed. Reg. at 77,817-30 (Appendix, Table H); 86 Fed. Reg. at 65,969-97 (Appendix 2). These activities have been developed based on a wide range of sources, including input from stakeholders, internal research and review, and comments received in response to rulemakings. *See, e.g.,* 81 Fed. Reg. at 77,190.

CMS determined to allot a relative weight of either "high" or "medium" to each improvement activity. 81 Fed. Reg. at 77,015. CMS further established that, to obtain full credit in the improvement activities performance category, a professional must complete either two high-weighted activities, four medium-weighted activities, or one high-weighted and two medium-weighted activities, although there are lower requirements for certain eligible clinicians, such as small or rural practices. 42 C.F.R. § 414.1380(b)(3). Each activity must be conducted for at least a continuous ninety-day period during the performance year. *Id.* § 414.1320. For the current 2023 performance period, there are 104 widely varying improvement activities from which a clinician

may choose to obtain credit under this performance category. *See* https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2023 (last visited July 17, 2023).

III. 2021 RULEMAKING

On January 20, 2021, the President issued Executive Order ("EO") 13,985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 Fed. Reg. 7009 (Jan. 25, 2021). This EO directed the federal government to "advanc[e] equity" by undertaking a variety of measures to "recognize and work to redress inequities in [federal] policies and programs that serve as barriers to equal opportunity." *Id.* It observed that "[e]qual opportunity is the bedrock of American democracy, and our diversity is one of our country's greatest strengths" but that "[e]ntrenched disparities in our laws and public policies, and in our public and private institutions, have often denied that equal opportunity to individuals and communities." *Id.* The EO defined "equity" to mean "the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment" and listed examples of such underserved communities. *Id.*

Subsequently, on July 23, 2021, CMS proposed adding an improvement activity to its inventory in the "Achieving Health Equity" subcategory titled "create and implement an anti-racism plan." 86 Fed. Reg. 39,104, 39,345, 39,855 (July 23, 2021), AR0241-44. This activity aims "to address systemic inequities, including systemic racism, as called for in Executive Order 13985." *Id.* at 39,855, AR0244. CMS explained that "[t]his activity begins with the premise that it is important to acknowledge systemic racism as a root cause for differences in health outcomes between socially-defined racial groups." *Id.* CMS further explained that "[t]his improvement activity acknowledges it is insufficient to gather and analyze data by race, and document disparities

by different population groups," *id.* at 39,345, AR0243, and "is intended to help clinicians move beyond analyzing data to taking real steps to naming and eliminating the causes of the disparities identified." *Id.* at 39,855, AR0244.

CMS received comments largely expressing support for the proposal to adopt this improvement activity, and for the high weight assigned to it, although a few comments raised some implementation issues. AR0031-240. The plaintiff States did not comment on the proposed rule. CMS responded to the comments and finalized the improvement activity in the subsequent final rule, 86 Fed. Reg. at 64,996, AR0001-6. As finalized, the activity is described as follows:

> Create and implement an anti-racism plan using the CMS Disparities Impact Statement or other anti-racism planning tools. The plan should include a clinic-wide review of existing tools and policies, such as value statements or clinical practice guidelines, to ensure that they include and are aligned with a commitment to anti-racism and an understanding of race as a political and social construct, not a physiological one.
>
> The plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps. This may also include an assessment and drafting of an organization's plan to prevent and address racism and/or improve language access and accessibility to ensure services are accessible and understandable for those seeking care. The MIPS eligible clinician or practice can also consider including in their plan ongoing training on anti-racism and/or other processes to support identifying explicit and implicit biases in patient care and addressing historic health inequities experienced by people of color. More information about elements of the CMS Disparities Impact Statement is detailed in the template and action plan document at https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.

86 Fed. Reg. at 65,970, AR0005-0006.

IV. THIS CASE

The current Plaintiffs are seven states, Mississippi, Alabama, Arkansas, Kentucky, Louisiana, Missouri, and Montana. In their First Amended Complaint, according to their own characterization, Plaintiffs raise "one claim"—that the new improvement activity is *ultra vires* as outside the bounds of the authority provided CMS in MACRA. Mem. of Law in Support of Pls.' Mot. for Summ. J. ("Pls.' Mem.") at 6, ECF No. 79; Am. Compl. ¶ 60. Defendants previously moved to dismiss the First Amended Complaint for lack of standing, or, in the alternative, on the ground that the statutory bar in 42 U.S.C. § 1395w-4(q)(13)(B)(iii) precluded judicial review. *See* ECF Nos. 36 & 37. The Court denied the motion to dismiss for lack of standing as to the States, holding that the States "have carried their burden at the pleading stage to clearly allege facts that establish each element of standing by demonstrating the harm to their sovereign interest in the enforcement of their laws." *Colville*, 2023 WL 2668513, at *18. The Court also held that the statutory review bar "does not preclude judicial review of the question whether the promulgated activity falls within the statutory definition of a 'clinical practice improvement activity.'" *Id.* at *19 (citation omitted). The parties have now both moved for summary judgment.

LEGAL STANDARDS

Summary judgment is appropriate if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Hanks v. Rogers*, 853 F.3d 738, 743 (5th Cir. 2017) (citation omitted); *see also McClendon v. City of Columbia*, 305 F.3d 314, 322 (5th Cir. 2002) (en banc). Where "the disputed issue in th[e] case is purely legal, it [is] appropriately resolved through summary judgment." *Neff v. Am. Dairy Queen Corp.*, 58 F.3d 1063, 1065 (5th Cir. 1995).

At the summary judgment stage, a plaintiff "can no longer rest on . . . 'mere allegations'" as to standing but must "'set forth' by affidavit or other evidence 'specific facts'" to meet his burden. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (citing Fed. R. Civ. P. 56(e)); *see also Time Warner Cable, Inc. v. Hudson*, 667 F.3d 630, 636 (5th Cir. 2012) (Though "general allegations may suffice for a motion to dismiss," "specific facts must be adduced to survive summary judgment."). If plaintiff is unable to set forth specific facts to prove each element of standing, the Court lacks jurisdiction to address the merits of the case. *See Steel Co. v. Citizens for a Better Envt.*, 523 U.S. 83, 101 (1998); *Ford v. NYLCare Health Plans of Gulf Coast, Inc.*, 301 F.3d 329, 332-33 (5th Cir. 2002).

ARGUMENT

I. PLAINTIFF STATES HAVE FAILED TO CARRY THEIR BURDEN TO ESTABLISH STANDING AT THE SUMMARY JUDGMENT STAGE

The doctrine of constitutional standing, an essential aspect of the Article III case-or-controversy requirement, demands that a plaintiff have "a personal stake in the outcome of the controversy [so] as to warrant his invocation of federal-court jurisdiction." *Warth v. Seldin*, 422 U.S. 490, 498 (1975) (citation omitted). At its "irreducible constitutional minimum," the doctrine requires a plaintiff, as the party invoking the Court's jurisdiction, to establish three elements: (1) a concrete and particularized injury-in-fact, either actual or imminent; (2) a causal connection between the injury and defendants' challenged conduct, such that the injury is fairly traceable to the challenged action of the defendant; and (3) a likelihood that the injury suffered will be redressed by a favorable decision. *Defs. of Wildlife*, 504 U.S. at 560.

Plaintiffs have failed to carry their burden to establish standing at the summary judgment stage. First, Plaintiffs have not identified a cognizable injury for Article III standing. The States

rely only on the asserted harm to a sovereign interest they possess in their antidiscrimination laws.[2] *See* Pls.' Mem. at 13. But a state's interest in its laws does not permit it to challenge any allegedly conflicting federal law. The States' standing theory in this case, at bottom, is one of *parens patriae*. That is, the States assert their interest in protecting their citizens from discrimination through their laws. It is a "settled rule," however, that states cannot assert antidiscrimination interests "on behalf of [their] citizens because 'a State does not have standing as *parens patriae* to bring an action against the Federal Government.'" *Brackeen*, 143 S. Ct. at 1640 (quoting *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982)) (cleaned up). Just last month, the Supreme Court rejected Texas's similar attempt to establish standing to challenge the requirements of the Indian Child Welfare Act ("ICWA") based on an alleged conflict between the ICWA and the state's commitment to antidiscrimination. *See Brackeen*, 143 S. Ct. at 1640. Specifically, Texas pointed to a conflict between ICWA and a state law prohibiting discrimination—like the State plaintiffs in this case—as well as a state constitutional provision. Reply Brief for Petitioner, the State of Texas, *Haaland v. Brackeen*, 21-376 (Oct. 3, 2022). The Supreme Court concluded that these alleged conflicts are "not the kind of 'concrete' and 'particularized' 'invasion of a legally protected interest' necessary to demonstrate an 'injury in fact.'" *Id.* (quoting *Defs. of Wildlife*, 504 U.S. at 560). *Brackeen* controls; as Texas's interest in its antidiscrimination laws was not cognizable, Plaintiffs' interest in their antidiscrimination laws are not cognizable. *See id.* *Brackeen* thus displaces this Court's earlier reliance on *Snapp* to conclude that the States plausibly alleged they were harmed because the improvement activity

[2] The States have waived any argument that they have suffered a fiscal injury. *See* Pls.' Mem. at 13.

"interferes" with their laws prohibiting discrimination. *See Colville*, 2023 WL 2668513, at *15 (citing *Snapp*, 458 U.S. at 601).

Second, in their summary judgment motion, Plaintiffs rest on the allegations in their Amended Complaint rather than introduce any *evidence* of how they enforce their antidiscrimination laws in the healthcare setting. This failure is an independent reason to grant summary judgment to Defendants. The States rely exclusively on the Court's order on Defendants' motion to dismiss. But, that order (properly) considered only the allegations in the Amended Complaint. *Colville*, 2023 WL 2668513, at *18. While "general allegations may [have] suffice[d] for a motion to dismiss," Plaintiffs must introduce "specific facts" about the impact of the challenged improvement activity on their enforcement of their antidiscrimination laws "to survive summary judgment." *Time Warner Cable, Inc.*, 667 F.3d at 636.[3] They have not done so.[4] Their failure suffices for the Court to enter summary judgment for Defendants.

Third, even if Plaintiffs had introduced evidence of an injury in fact, their harms would not be traceable to the improvement activity or redressable by the Court. The States' theory of harm depends on the actions of third parties not before the Court, that is, clinicians who choose to create and implement anti-racism plans that may conflict with the States' antidiscrimination laws. A plaintiff can establish neither the necessary causal connection between an alleged injury and defendants' conduct nor the necessary redressability where plaintiff's allegations rely on the independent and speculative actions of third parties not before the Court. *See Defs. of Wildlife*, 504 U.S. at 562; *Little v. KPMG LLP*, 575 F.3d 533, 541 (5th Cir. 2009). Here, Plaintiffs'

[3] Presumably, the States have discretion in how they enforce their laws.

[4] Had Plaintiffs attempted to introduce such evidence with their early-filed motion for summary judgment, Defendants would have sought discovery about their alleged injury. *See* Fed. R. Civ. P. 56(d).

allegations depend on "several layers of decisions by third parties," *Little*, 575 F.3d at 541—namely, clinicians. The States' suggestion that some clinicians will implement plans in a manner that conflicts with state antidiscrimination laws is part of a hypothetical chain of events involving independent third parties that is both speculative and too "attenuated" and "weak" to support standing. *See Allen v. Wright*, 468 U.S. 737, 759 (1984) (finding chain of causation too weak where it "involve[d] numerous third parties . . . who may not even exist in respondents' communities and whose independent decisions may not collectively have a significant effect"). And, again, the States have not introduced any evidence of anti-racism plans (or any other evidence) that violate their state laws.

Finally, "[s]pecial solicitude" does not remedy the States' standing deficiencies, and they have not attempted to establish another theory of redressability. As an initial matter, "special solicitude" does not relieve states of their obligation to establish a cognizable injury in fact. *See Gov't of Manitoba v. Bernhardt*, 923 F.3d 173, 182 (D.C. Cir. 2019) (noting that, in *Massachusetts v. EPA*, 549 U.S. 497 (2007), the State was "entitled to 'special solicitude' because" it had "a quasi-sovereign interest in 'preserv[ing] its sovereign territory,'" but it still demonstrated "its own harm to establish an injury-in-fact"). Next, the Supreme Court has declined to apply "special solicitude" in recent cases, with three Justices suggesting lower courts should stay away from the doctrine. *See United States v. Texas*, 143 S. Ct. at 1977 (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment) ("Before *Massachusetts v. EPA*, the notion that States enjoy relaxed standing rules had no basis in our jurisprudence. Nor has 'special solicitude' played a meaningful role in this Court's decisions in the years since. . . . And it's hard not to think, too, that lower courts should just leave that idea on the shelf in future ones.") (cleaned up); *see also id.* at 1997 (Alito, J., dissenting) (suggesting *Massachusetts* has been "quietly interred"); *cf. id.* at

1975 n.6 (suggesting that further Justices had "disagreements" with *Massachusetts v. EPA*). In any event, at the summary judgment stage, Plaintiffs have not provided sufficient evidence of a quasi-sovereign injury, as explained above, or of a procedural right, both of which were required by earlier Fifth Circuit precedent regarding special solicitude. *See Texas v. United States*, 809 F.3d 134, 151-52 (5th Cir. 2015) (requiring two elements). "Special solicitude" cannot save Plaintiffs' standing theory.

II. CMS'S PROMULGATION OF THE ACTIVITY TO CREATE AND IMPLEMENT AN ANTI-RACISM PLAN WAS NOT *ULTRA VIRES*

The Court has already held that, in the context of this case, it has jurisdiction to review whether a promulgated activity falls within the statutory definition of a "clinical practice improvement activity," notwithstanding the judicial review bar in 42 U.S.C. § 1395w-4(q)(13)(B)(iii). *Colville*, 2023 WL 2668513, at *18-*20. Defendants continue to maintain that this review bar applies here to foreclose Plaintiffs' suit, and they incorporate their previous arguments thereon by reference. *See* Mem. in Support of Defs.' Mot. to Dism. Pls.' First Am. Compl. 21-29 (ECF No. 37). However, Defendants accept for the purposes of this motion the Court's prior conclusion that it has jurisdiction to determine whether the review bar applies and thus to address the merits of Plaintiffs' *ultra vires* claim, if it determines Plaintiffs have standing.

Even if Plaintiffs have standing, however, Defendants are still entitled to summary judgment because CMS's promulgation of the new activity to create and implement an anti-racism plan was not *ultra vires.* As further discussed below, there is ample evidence in the Administrative Record, as well as outside the record, that the creation and implementation of an anti-racism plan has been identified by "relevant eligible professional organizations and other relevant stakeholders . . . as improving clinical practice or care delivery" and has been determined by CMS to be, "when

effectively executed, . . . likely to result in improved outcomes." 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III). Therefore, adding the create and implement an anti-racism plan improvement activity to the improvement activities inventory—providing a financial incentive to engage in such an activity—was within CMS's statutory authority.

At the outset, "[t]o determine 'the authority that Congress has provided,' [the court] examine[s] an agency's authorizing statutes." *Midship Pipeline Co., L.L.C. v. FERC*, 45 F.4th 867, 875 (5th Cir. 2022) (quoting *Nat'l Fed'n of Indep. Bus. v. Dep't of Labor, Occupational Safety & Health Admin.*, 142 S. Ct. 661, 665 (2022)). In doing so, the Court must give deference to the defendant agency's interpretation of any ambiguity or gaps in those statutes under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *See City of Arlington, Tex. v. FCC*, 569 U.S. 290, 296-97 (2013) (court must defer under *Chevron* to an agency's interpretation of a statutory ambiguity that concerns the scope of the agency's statutory authority). This includes deferring to the agency's determination of the scope of broad definitional terms in the statute, particularly where, as here, the agency has been granted explicit authority to regulate. *See Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 165, 167 (2007) (granting deference to agency's determination of "whether to include workers paid by third parties" within the scope of the statutory phrases "domestic service employment" and "companionship services," finding that "Congress entrusted the agency to work out" "the details" of the "broader definition"). Under *Chevron*, there is no distinction between *ultra vires* and other challenges because ultimately, the question as to every challenge to an agency's interpretation of a statutory ambiguity—"whether framed as an incorrect application of agency authority or an assertion of authority not conferred—is always whether the agency has gone beyond what Congress has permitted it to do." *Arlington*, 569 U.S. at 297-98. *Chevron*'s standard therefore applies here, and Defendants' interpretation of

what relates to "clinical practice or care delivery" or "improve[s] outcomes," or any of the other statutory terms, is entitled to deference.

In addition, the Court's review must be based on the entire administrative record and is not limited by the arguments that the parties may have previously raised in connection with the earlier motions, as Plaintiffs suggest (Pls.' Mem. at 10). *See Ludwick v. Merit Sys. Prot. Bd.*, No. SA-21-CV-0786-JKP, 2023 WL 1087889, at *6 (W.D. Tex. Jan. 27, 2023) ("The Court may take arguments from the parties, but the administrative record is what provides the necessary information to conduct its judicial review."); *La. Crawfish Producers Ass'n-West v. Mallard Basin, Inc.*, Nos. 6:10-cv-01085-RFP-PJH; 6:11-cv-00461-RFD-PJH, 2014 WL 782984, at *4 (W.D. La. Feb. 24, 2014) ("The district court may not rely on counsel's statements as to what was in the record; the district court itself must examine the administrative record and itself must find and identify facts that support the agency's action.") (quoting *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1576 (10th Cir.1994)).

Plaintiffs contend that the agency decision to provide an upward payment adjustment based on the activity of creating and implementing an anti-racism plan is *ultra vires* because (1) the activity does not relate to "clinical practice or care delivery" and (2) the rule fails to identify any "relevant eligible professional organizations and other relevant stakeholders" that have identified the activity as improving clinical practice or care delivery. Pls.' Mem. at 9-10. Plaintiffs are wrong on both counts.

Taking Plaintiffs' complaints in reverse order, first, the comments submitted in response to CMS's proposed rule establish "that relevant eligible professional organizations and other relevant stakeholders" identified the activity of creating and implementing an anti-racism plan "as improving clinical practice or care delivery." 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III). For example,

the Intersocietal Accreditation Commission (an accreditation standards development organization) "recommends the inclusion of the proposed improvement activity titled 'create and implement an anti-racism plan,'" which it stated "is an opportunity to recognize clinicians for developing and implementing processes to reduce racism and discrimination to ensure equitable health care." AR0215. Similarly, the American Academy of Dermatology Association commented that the create and implement an anti-racism plan improvement activity has "important objectives grounded in better meeting the diverse needs of patients and clinicians and [is] commendable," AR0201, and the Coalition to Transform Advanced Care ("C-TAC") stated that it "feel[s] these changes will help to address inequity in the health care system," C-TAC Comments, at 4, https://downloads.regulations.gov/CMS-2021-0119-32235/attachment_1.pdf. Other professional organizations also supported the activity,[5] and no commenter opposed its addition. The plaintiff States did not provide any comment. In addition, other materials in the record reflect that other professionals have recommended anti-racism approaches. *See* AR2296 (a group of academics associated with the University of Ohio); AR2282 (Dr. Camara Phyllis Jones).

Second, the statute does not require that the activity be independently determined to "relate to clinical practice and care delivery," as Plaintiffs suggest, only that relevant stakeholders have *identified* it as improving those aspects (which, as explained above, they have) and that the Secretary has "determine[d]" that, when effectively executed, the activity "is likely to result in

[5] *See also* AR0046 (comment by the American College of Radiology "agree[ing] with including improvement activities in MIPS that address creating and implementing anti-racism plans"); AR0146 (comment by the Association of American Medical Colleges "agree[ing] that the inclusion of a proposed improvement activity titled 'create and implement an anti-racism plan' is an important activity that will address systemic racism as a root cause of inequity"); AR0191 (comment by the American Society for Radiation Oncology "support[ing] the addition of the proposed improvement activit[y]"); AR0291 (comment by MarsdenAdvisors "applaud[ing] CMS's proposal to include this IA in the inventory in 2022").

improved outcomes." This latter requirement has been satisfied because, in promulgating the activity, CMS stated that it "believe[s] this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes." 86 Fed. Reg. at 65,969, AR0005.

To the extent there is any requirement independent of the foregoing that the activity must "relate to" clinical practice or care delivery, the materials both within and (as described further below) outside the administrative record establish that creating and implementing an anti-racism plan relates to and may improve clinical practice or care delivery by fostering more racially and ethnically equitable health care. CMS starts by citing, as background, numerous reports establishing that health inequities between races and ethnicities are observed even after "controlling for multiple factors, such as age, sex, and comorbidities" and therefore that those inequities can be attributed "to broader structural, socioeconomic, political, and environmental factors that are rooted in years of systemic racism." AR0268, *cited at* 86 Fed. Reg. at 65,382, AR0002 n.170.[6] CMS then acknowledges that, "to achiev[e] equity in health care outcomes for Medicare beneficiaries," 86 Fed. Reg. at 65,383, AR0003, "it is insufficient to gather and analyze data by race, and document disparities by different population groups." 86 Fed. Reg. at 65,384, AR0004.

Accordingly, CMS identified the next step as "developing and disseminating solutions to achieve health equity." 86 Fed. Reg. at 65,383, AR0003. The administrative record materials establish that one such "solution" to the disparate clinical experience and care delivery experienced

[6] The role of "structural" or "systemic" racism and racial discrimination is also recognized in other reports. *See, e.g.*, AR0278 ("Several potential factors may contribute to racial and ethnic disparities in vaccination uptake, including, but not limited to, . . . persistent medical mistrust rooted in a history of racial discrimination and mistreatment in the health care sector."); AR01397 ("the racial differences found in large data sets most likely often reflect effects of racism").

by different population groups is the development of anti-racism plans. CMS stated that it believed its support of such plans through this new activity will likely result in improved outcomes "because it supports MIPS eligible clinicians in identifying health disparities and implementing processes to reduce racism and provide equitable quality health care." 86 Fed. Reg. at 65,969, AR0005. This conclusion is supported by the Administrative Record. *See, e.g.*, AR1398 (advocating "reconsidering race correction in order to ensure that our clinical practices do not perpetuate the very inequities we aim to repair."); *see also id.* ("Adopting activities to enhance patients' access to culturally and linguistically appropriate services is essential for reducing disparities and reaching the ultimate goal of building a health care system that delivers the highest quality of care to every patient, regardless of race, ethnicity, culture or language.").[7]

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[7] As noted in *Health Affairs Forefront*:

> Black patients are less likely to have their symptoms and pains given serious credence, less likely to receive evidence-based diagnostic testing and treatment, and more likely to be mislabeled and stereotyped by health care professionals due to implicit and explicit biases.
>
> As medical professionals, we take an oath to do no harm. It is therefore our professional and ethical obligation to dismantle systems that have structurally been designed to harm. This does not mean talking around social determinants of health or talking about diversity; it means actively working against racism, by evaluating curricula, practices, training models, behaviors, and actions through a lens of anti-racism.
>
> To this end, the Ohio State University Wexner Medical Center and Health Sciences Colleges have launched an Anti-Racism Action Plan and urgently call for other academic medical centers and health care serving institutions to follow suit.

J. Nwando Olayiwola et al., *Making Anti-Racism a Core Value in Academic Medicine*, Health Affairs Forefront, Aug. 25, 2020, at 2, AR2296.

Thus, the administrative record provides evidence of systemic racism in the health system and the current thinking expressed by relevant eligible professional organizations and other stakeholders regarding one way to improve the clinical practice experienced by and care delivered to people of color—through approaches focused on reducing disparities created by racism, such as anti-racism approaches.

Given this record, Plaintiffs cannot meet their burden to show that CMS acted outside of its statutory authority in creating this activity. To establish an *ultra vires* violation, Plaintiffs must show "a 'plain' violation of an unambiguous and mandatory provision of the statute," *Am. Airlines, Inc. v. Herman*, 176 F.3d 284, 293 (5th Cir. 1999), in other words, a "patent violation of agency authority." *N. Oaks Med. Ctr., LLC v. Azar*, No. 18-9088, 2020 WL 1502185, at *7 (E.D. La. Mar. 25, 2020) (quoting *Fla. Health Scis. Ctr. v. Sec'y of Health & Hum. Servs.,* 830 F.3d 515, 522 (D.C. Cir. 2016)); *see also Fed. Express Corp*, *v. U.S. Dep't of Com*., 39 F.4th 756, 765 (D.C. Cir. 2022) ("*[U]ltra vires* claimants must demonstrate that the agency has plainly and openly crossed a congressionally drawn line in the sand."). In other words, challengers must show more than the type of routine error in "statutory interpretation or challenged findings of fact" that would apply if Congress had allowed Administrative Procedure Act ("APA") review. *Fed. Express Corp*., 39 F.4th at 765 (quoting *Loc. 130, Int'l Union of Elec., Radio & Mach. Workers, AFL-CIO v. McCulloch*, 345 F.2d 90, 95 (D.C. Cir. 1965)). Plaintiffs have not shown that CMS has acted in "patent violation" of its authority to create new clinical practice improvement activities by including a new activity addressed to implementing plans focused on reducing health disparities created by racism.

Plaintiffs assert that the anti-racism plan activity will "inject race ideology" into medicine by encouraging discriminatory practices that may be necessary to create "equity." Pls.' Mem. at

5. They contend that the activity directs clinicians to prioritize certain racial and ethnic populations over others. *Id.* at 9. As a result, according to Plaintiffs, the activity does not in fact pertain to clinical care because it encourages providers to consider race in ways that have no "physiological" relevance. *Id.* at 5, 9.

However, Plaintiffs mischaracterize the nature of the "anti-racism plans" that the activity is designed to produce. Nothing in CMS's description of the activity suggests that clinicians should "prevent and address racism" by engaging in "present discrimination," as Plaintiffs assert. Plaintiffs repeatedly cite Kendi's formulation of "antiracism" to include "present discrimination," but CMS did not cite Kendi, and there are many other definitions of anti-racism. For example, "[a]nti-[r]acism is the practice of actively identifying and opposing racism. The goal of anti-racism is to actively change policies, behaviors, and beliefs that perpetuate racist ideas and actions." Boston Univ. Cmty. Serv. Ctr., What is Anti-Racism?, https://www.bu.edu/csc/edref-2/antiracism/ (last visited July 24, 2023).

CMS's focus is on "provid[ing] equitable quality health care." AR006. Addressing disparities experienced by one group does not mean discriminating against or lessening the treatment afforded other groups. And Plaintiffs misread CMS's explanation that race is a "political and social construct, not a physiological one"—this statement is simply meant to summarize years of studies showing that racial inequities in health outcomes may be due as much to *racism* as to *race* and related "social determinants." *See, e.g.,* AR0797 (reporting that "observed differences by race and ethnicity may represent differences in the quality of care received, including differences related to poor communication, poor cultural competence, discrimination, and bias"); AR2296 ("[I]n communities of color, social determinants often equate to disparity, and are, in many cases, institutional expressions of racism, oppression, sexism, injustice, and inequity."); *see*

also AR2286 (discussing debate between those arguing that that "racial and ethnic categories reflected underlying population genetics and could be clinically useful" and those "cast[ing] doubt on race-based medicine" amid "mounting evidence that race is not a reliable proxy for genetic difference"); Soc'y of Gen. Internal Med. Comments, at 6, https://downloads.regulations.gov/CMS-2021-0119-32499/attachment_1.pdf ("[R]ace and ethnicity are not the social determinants of health (SDOH) which are the direct primary mediators of inequities and poor health outcomes."); Ass'n of Black Cardiologists Comments, at 4 https://downloads.regulations.gov/CMS-2021-0119-33947/attachment_1.pdf ("Everyday racism, in work or in health care, results in higher rates of coronary heart disease, diabetes, stroke and end stage renal disease."). CMS's statement to the effect that race may have no or little physiological significance does not imply that it would be acceptable for clinicians to discriminate on the basis of race, as Plaintiffs assert. Nor should the Disparities Impact Statement's reference to "prioritiz[ing]" be read to sanction "discrimination" against populations "not prioritized." In this context, the "priority" population is simply the population affected by the health disparity the clinician desires to "address" and not a statement that that population is more important than another. *See* https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.

Plaintiffs also contend that the anti-racism plan activity is not like the examples enumerated in the statute and therefore is *ultra vires* for that reason. *See* Pls.' Mem. 2, 10 (discussing 42 U.S.C. § 1395w-4(q)(2)(b)(ii)). The statute prefaces these examples with the words "include," "at least," and "such as," indicating that the examples are meant to be nonexhaustive. *See Samantar v. Yousuf*, 560 U.S. 305, 317 (2010) ("It is true that use of the word 'include' can signal that the list that follows is meant to be illustrative rather than exhaustive."); *Cox v. City of Dallas*, 256 F.3d 281, 293 (5th Cir. 2001) (citing *Cobell v. Norton*, 240 F.3d 1081, 1100 (D.C. Cir. 2001) ("It is

hornbook law that the use of the word including indicates that the specified list . . . that follows is illustrative, not exclusive.")). Plaintiffs argue that creation and implementation of an anti-racism plan is not like the examples listed, stating that the examples are not "remotely related to nonphysiological considerations of race or prioritizing some people over others based on race." Pls.' Mem. at 10. However, as stated above, Plaintiffs' description of this activity is based on a misunderstanding of its nature, which is, like the examples in the statute, ultimately focused on health outcomes. In any event, the examples cited in the statute span a wide spectrum of activities (from the relatively discrete activity of "same day appointments" to broader, more open-ended activities such as "establishment of care plans for individuals with complex care needs" or "using shared decision-making mechanisms"), and the canon Plaintiffs seek to apply here, *noscitur a sociis*, is invoked only "when a string of statutory terms raises the implication that the 'words grouped in a list should be given related meaning.'" *S.D. Warren Co. v. Me. Bd. of Envtl. Prot.*, 547 U.S. 370, 378 (2006) (quoting *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 36 (1990)). Given the wide variety of activities listed (let alone that it is not a "string" of terms), it cannot be concluded that Congress believed or intended to suggest that there was any common attribute among the activities, other than their general relation to clinical practice or care delivery. Moreover, Plaintiffs do not explain how creating and implementing an anti-racism plan to "eliminat[e] the causes of [health] disparities" is so different from activities like "establishment of care plans for individuals with complex care needs" or "using shared decision-making mechanisms" as to render the anti-racism plan activity *ultra vires*. It is not.

The agency's actions are further supported by evidence outside of the record, which courts in this Circuit may consider in evaluating an *ultra vires* claim. As a general rule, "[j]udicial review of agency action is . . . limited to an examination of the agency record." *Baker v. Bell*, 630 F.2d

1046, 1051 (5th Cir. 1980); *see also Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420 (1971) (holding that courts must limit their review to the administrative record before the agency at the time the decision was made). However, courts in this Circuit have held that claims that do not arise within the APA context are not bound by the record rule. *Texas v. Biden*, No. 2:21-CV-00067-Z, 2021 WL 4552547, at *6 (N.D. Tex. July 19, 2021). Plaintiffs' *ultra vires* clam is one such claim. *Texas v. U.S. Dep't of Homeland Sec.*, No. 6:23-CV-00007, 2023 WL 2842760, at *1 (S.D. Tex. Apr. 7, 2023). Conceptually, because the issue in an *ultra vires* claim is whether the agency had the authority to act as it did, not whether it exercised that authority properly in compliance with the APA, the administrative record is not dispositive. Rather, as long as the agency *could* have found that the activity met the statutory definition, it possessed the authority to promulgate the activity. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 690 (1949) (explaining that the *ultra vires* doctrine is grounded on "the officer's lack of delegated power" and not "[a] claim of error in the exercise of that power").

Therefore, the Court's review should not be limited to the administrative record, and it may consider extra-record evidence regarding the fit between an anti-racism plan and the statutory criteria. Here, there is ample extra-record evidence that racism within the medical system contributes to health disparities between races. *See* Mot. to Intervene, at 3, 7, and sources cited therein (ECF No. 62). There is also evidence showing that anti-racism programs directed at addressing racism are likely to address these disparities and thereby improve treatment outcomes. *See* Thatcher Decl. ¶¶ 14-17 (discussing impact of anti-racism interventions evaluated in one study, which showed that "a racial equity plan had a substantial impact on successful treatment"), ECF No. 62-9; *id.* ¶ 23 (stating that one physician reported that "his medical practice has meaningfully improved as a result of attending . . . anti-racism trainings"). *See generally, e.g.*, Simelton Decl.

¶ 5 ("Reducing racial discrimination and insensitivity in the medical profession would likely improve the quality of care that some of our members receive."), ECF No. 62-2.

Finally, Defendants argue, for the purpose of preserving the issue for further review, that the Court should decline to review Plaintiffs' claim for one additional reason—that Plaintiffs have waived any challenge that CMS's actions are *ultra vires* because neither they nor any other commenter raised this issue during the notice-and-comment period of this rulemaking. Most courts to consider the issue require issues to have been presented to the agency before a court may consider them. *See Koretoff v. Vilsack*, 707 F.3d 394, 398 (D.C. Cir. 2013) ("We require 'the argument [petitioner] advances here' to be raised before the agency, not merely the same general legal issue," including petitioner's argument as to the agency's statutory authority.); *Universal Health Servs., Inc. v. Thompson*, 363 F.3d 1013, 1020 (9th Cir. 2004); *1000 Friends of Md. v. Browner*, 265 F.3d 216, 228 n.7 (4th Cir. 2001) (stating in dictum that, outside the Fifth Circuit, the waiver rule "has been rather routinely applied in [rulemaking] cases"); *Mich. Dep't of Envtl. Quality v. Browner*, 230 F.3d 181, 183 n.1 (6th Cir. 2000); *USA Grp. Loan Servs. v. Riley*, 82 F.3d 708, 713–14 (7th Cir. 1996); *N.M. Health Connections v. HHS*, 340 F. Supp. 3d 1112, 1167 (D.N.M. 2018) (discussing application of waiver rule). The Fifth Circuit's "waiver precedents in this area are admittedly in conflict." *Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1022 n.23 (5th Cir. 2019). Most recently, the Fifth Circuit stated that it "must follow the earlier precedent"—*City of Seabrook v. EPA*, 659 F.2d 1349, 1360-61 (5th Cir. Unit A Oct. 1981)—and accordingly found no waiver. *Sw. Elec. Power Co.*, 920 F.3d at 1022 n.23. *But see BCCA Appeal Grp. v. EPA*, 355 F.3d 817, 828 (5th Cir. 2003) (acknowledging conflict but distinguishing *City of Seabrook* and finding waiver, stating that "this court will not consider questions of law which were neither presented to nor passed on by the agency"). Although this Court, to the extent this case

indistinguishable, is bound by *Southwestern Electric Power*, the Fifth Circuit could re-consider the issue. Accordingly, if the Court does not otherwise find that it lacks jurisdiction, Defendants ask for a ruling on this issue.

III. ANY RELIEF MUST BE TAILORED ONLY TO REDRESS PLAINTIFFS' INJURIES

Even if the States are entitled to some relief, which they are not, the Court should not vacate the improvement activity or issue a nationwide injunction. Rather, remand to the Secretary to address the improvement activity through rulemaking would be the proper remedy. While Fifth Circuit precedents identify vacatur as an available remedy for a successful APA challenge to a regulation, *see, e.g.*, *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 374-75 (5th Cir. 2022), the APA itself does not reference vacatur, instead remitting plaintiffs to traditional equitable remedies like injunctions, 5 U.S.C. § 703, and there is little indication that Congress intended to create a new and radically different remedy in providing that courts reviewing agency action should "set aside" agency "action, findings, and conclusions," *id*. § 706(2). *See Texas*, 143 S. Ct. at 1980-83 (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment) (detailing "serious" arguments that "warrant careful consideration" as to whether the APA "empowers courts to vacate agency action").

In any event, the Fifth Circuit has treated universal vacatur of agency action as a discretionary equitable remedy—not a remedy that is automatic or compelled. *See, e.g*, *Cent. & S. W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000) (remanding without vacatur in light of "disruptive" consequences of vacatur). And in this case, any remedy should be limited to remand to the Secretary without vacating the challenged activity. Vacatur of the challenged activity could unexpectedly leave clinicians facing lower reimbursement from HHS for the past

payment years and the current payment year and could even require the Defendants to attempt to recoup spent funds. These costs could ultimately be passed along to patients. This regulatory hole would be disruptive and is reason to remand the challenged activity without vacatur. These equitable interests counsel heavily in favor of remand without vacatur. *Id.*; *see, e.g.*, *Bridgeport Hosp. v. Becerra*, No. 1:20-CV-01574 (CJN), 2022 WL 4487114, at *4 (D.D.C. July 27, 2022) (remanding without vacatur HHS's budget neutrality policy because vacatur "would create a regulatory vacuum with respect to payment calculations for fiscal year 2020"), appeals pending, Nos. 22-5249, 22-5269 (D.C. Cir.).

At a minimum, any injunctive relief should be limited to the states that are parties to this lawsuit and that have pertinent antidiscrimination laws. *See* Pls.' Mem. at 14 n.2 (identifying only five state plaintiffs with allegedly conflicting antidiscrimination laws). Ordinarily principles of Article III standing and equity generally require that a court tailor remedies to address the plaintiff's injury. *See, e.g.*, *Gill v. Whitford*, 138 S. Ct. 1916, 1933 (2018); *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994). Courts should thus "ask[] whether party-specific relief can adequately protect the plaintiff's interests;" if so, entering "broader relief is an abuse of discretion." *Texas*, 143 S. Ct. at 1980, 1986 (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment). Equitable relief as to the challenged improvement activity only with respect to the plaintiff states that have conflicting antidiscrimination laws would remedy the injuries they claim, and relief that extends beyond these parties, including a nationwide vacatur or injunction, would be improper.

CONCLUSION

For the reasons set forth above, Defendants are entitled to summary judgment, and Plaintiffs' motion for summary judgment should be denied.

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Respectfully submitted,

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